Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-07-23
Investment Auto Submission Date: 2012-02-24
Date of Last Investment Detail Update: 2012-02-24
Date of Last Exhibit 300A Update: 2012-07-23
Date of Last Revision: 2012-07-23

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA ORA Regulatory Business Information Services

2. Unique Investment Identifier (UII): 009-000005316

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

RBIS provides data availability and data quality for all of the ORA regulatory activities. RBIS supports all FDA Field activities including domestics, imports, and enforcement. It aligns directly with Strategic Goal 2, Objective C of the HHS strategic plan: Advance Scientific Knowledge and Innovation; Invest in the regulatory sciences to improve food and medical product safety and enables FDA Centers to meet FDA Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain. RBIS includes 1 Online Reporting, Analysis, and Decision Support System (ORADSS): a centralized data warehouse and reporting structure focused primarily on data availability for historical information. 2 Firms Master List Services (FMLS): a master, authoritative source focused primarily on data quality for approximately 5 million foreign and domestic firms which produce products regulated by the FDA. The reporting and firm information are used throughout the ORA work flows to support import screening, inspections, investigations, field exams, sample collections, sample analysis, recalls, case management, other compliance activities, and work planning. This information is used both to support every-day operations and to analyze and plan for the future. Primary beneficiaries of RBIS are the FDA personnel who access these integrated systems for analysis and decision-making that is used to protect public health and safety and communicate to the public. FDA management also benefits from the information RBIS provides to help in planning and identifying risks. Over 6,000 users throughout FDA use

RBIS. RBIS is closely coupled with two other major ORA investments, ALM and MARCS. ALM provides functionality for ORA laboratories and quality. MARCS is the primary IT system for all regulatory activities outside of the labs and quality. Together, these three investments provide for all of the regulatory workflows of ORA. RBIS also interacts with FURLS, eLIST, and a number of smaller systems at FDA. In addition, RBIS interacts with Dunn and Bradstreet (D&B) information so that FDA can access the large data set of firm information held by D&B to improve domestic and foreign firm data quality.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

RBIS fills the current performance gap by providing for 1 Standardized access to reports and other historical information. ORADSS contains a centralized data warehouse that includes subsets of information pertaining to particular activities. This is made available to non-technical users via COTS solutions. Users can access canned reports or create ad hoc reports without needing specialized knowledge of the underlying data structures. This allows the data to be made available to the largest possible user audience. More advanced users can query the data warehouse directly to support data mining and analysis. 2 Standardized firm information that allows for reliable firm identification. FMLS contains information on some 5 million firms. FDA must maintain information on companies around the world that manufacture, produce, or process regulated items. Within this universe of firms, there are always new companies, companies going out of business, and companies that are merging. FDA receives approximately 10,000 new or unrecognized firms per week. Sometimes these are not new firms, but firms that FDA already has in its database that need to be matched. This is especially true of foreign firms in nations that do not utilize a Latin alphabet. FMLS is continually used to match, clean up, delete, merge, and unmerge firm names in order to provide FDA with an accurate list of the firms that are producing regulated items. This is accomplished through using a set of rules to manage firms, fuzzy logic, and manual analysis. This emphasis on the data quality of the firms tracked by FDA supports all of the regulatory workflows of ORA. If RBIS is not fully funded then data availability, data quality, or both will suffer. The functionality provided by RBIS is closely tied to that provided by ALM or MARCS. Information generated in ALM or MARCS will find its way into RBIS. This is actively used by FDA personnel in order to support the every day operations of ORA and the Centers.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

RBIS has the following accomplishments for PY: Improved data mart capabilities for the ORA laboratories allowing for access to near real time decision support information to give ORA the information to respond more quickly to public health emergencies. Improvements in the firm survivorship rules to reduce the number of duplicate firms, especially amongst foreign firms, to improve risk-based targeting and allocation of resources. Integration with D&B to support data quality of firm information. Improved support for data sharing by the Centers to ORA. Updated a number of existing reports. Added new reports requested by users. Merged or deleted reports not used or rarely used. Upgraded to newer version of COTS solution. Migrated older reports to the newer COTS solution. Resolved over 100 change requests. Awarded an integrated contract replacing four previous contracts in order to improve

management efficiency.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

RBIS plans to accomplish in CY (FSMA requirements (question 3.a) are implicit throughout this section): An analysis and evaluation of the current data and system architectures for ORADSS and FMS. This will result in a recommendation to improve and modernize RBIS. Modifications, including reports, to support new functionality in MARCS including RAC, PREDICT, FMS, DGS, PS, DLCMS, UWES, FWM, WAAM, EM, and RADs. Much of the development in RBIS is driven by changes in MARCS. Reporting to support legacy MARCS CMS. Improved firm information verification to support MARCS PREDICT. Integration with ALM QMiS. Enhanced mapping functionality (GIS). Improved integration with FURLS. Integration with eLIST. Improved integration with D&B. Continued firms clean up to support data quality. RBIS plans to accomplish in BY: Implementation of an improved architecture for ORADSS and FMLS. Modifications, including reports, to support new functionality in MARCS including PS, DLCMS, UWES, FWM, WAAM, EM, RADs, PNM, ITACS, EOM, IAM, MPG, ALS, and LRS. Much of the development in RBIS is driven by changes in MARCS. Continued integration with eLIST. Improved integration with D&B. Continued firms clean up to support data quality. Modifications, including reports, to support the new ALM LIMS.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2010-09-30

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$4.5	$0.0	$0.0	$0.0
DME (Excluding Planning) Costs:	$28.7	$5.3	$6.0	$7.2
DME (Including Planning) Govt. FTEs:	$1.2	$0.2	$0.2	$0.2
Sub-Total DME (Including Govt. FTE):	$34.4	$5.5	$6.2	$7.4
O & M Costs:	$13.4	$3.2	$4.3	$4.5
O & M Govt. FTEs:	$1.2	$0.2	$0.2	$0.2
Sub-Total O & M Costs (Including Govt. FTE):	$14.6	$3.4	$4.5	$4.7
Total Cost (Including Govt. FTE):	$49.0	$8.9	$10.7	$12.1
Total Govt. FTE costs:	$2.4	$0.4	$0.4	$0.4
# of FTE rep by costs:	4	3	3	3
Total change from prior year final President's Budget ($)		$-0.7	$0.3	
Total change from prior year final President's Budget (%)		-6.91%	2.96%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

Funding levels have been increased in order to address the new requirements from the Food Safety and Modernization Act (FSMA). RBIS will be modified to support MARCS for functionality defined in the following areas of FSMA: Sec. 103 Sec. 104 Sec. 105 Sec. 106 Sec. 107 Sec. 110 Sec. 111 Sec. 113 Sec. 114 Sec. 115 Sec. 201 Sec. 202 Sec. 204 Sec. 205 Sec. 206 Sec. 207 Sec. 210 Sec. 301 Sec. 302 Sec. 303 Sec. 304 Sec. 306 Sec. 307 Sec. 308 Sec. 309

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded	7524	HHSF223201000047I									
Awarded	7524	HHSF223200950015I									
Awarded	7524	HHSF223200850026C									
Awarded	7524	IND11PX19157									

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-07-23

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
287623	FDA ORA RBIS Center and External Integration	This deals with some of the integration points that RBIS has with systems outside of the program. In particular, this will improve integration with MARCS Center Views and Standardized Evidence and Reference Services (SERS) and ORADSS. It will also implement integration with MARCS Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT) with FMLS.			
287707	FDA ORA RBIS Data Warehouse, Data Marts, and Universes	The Online Reporting Analysis and Decision Support System (ORADSS) within RBIS contains a Data Warehouse (DW) at its core. This provides access to historical data from a number of systems, such as MARCS. The DW further contains a reporting database that retains the schema from the Online Transaction Processing (OLTP) database from which information was originated. The DW has			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		information in it that has been transformed into a star schema so that it is a Decision Support System (DSS). In addition, for some user communities, it is much more effective for them to only have to deal with a subset of all of the data in the DW. For such user communities, ORADSS has a number of Data Marts (DM) that certain designated users can use for querying. These are also used to support universes for reporting. ORADSS uses a COTS, Business Objects (BO), as a reporting tool. BO utilizes universes as a meta-data layer that allows for an abstraction of the underlying schema, table names, row names, and data types so that non technical users can access this data more easily. The universe structures may then be used to build reports. End users typically interact with the reports, but there are a number of end users who need to delve more deeply into the data than is allowed by a report. These users may access the DW, DMs, or universes directly depending on their particular needs. This project specifically focuses on providing better data availability for compliance users, MARCS Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT), and an organizational group in ORA that tracks resources and conducts work force planning.			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
287708	FDA ORA RBIS Firm Master List Services (FMLS) Enhancements	FMLS in RBIS is closely aligned with Firm Management Services (FMS) in MARCS. FMLS does the back end heavy lifting work for managing firm information. This includes receiving firm information from registration and listing from the FDA Unified Registration and Listing System (FURLS). FURLS is being partially replaced by eLIST. FMLS will integrate with eLIST (no acronym). The firm data is built around Firm Establishment Identifiers (FEIs). These define a location and a product or a set of products. A large company may have multiple FEIs if it has multiple physical locations and/or produces different products that are regulated by FDA. This information is always changing as firms and market conditions change. In addition, foreign firms that do not use a Latin alphabet present a particular problem as words can be transliterated into English in different ways. If this is left unchecked, it causes a proliferation of FEIs that are not all that useful in identifying what firm is what. To address this, FMLS employs Dataflux, a COTS, in implementing survivorship rules that are used to clean up this firm data and consolidate and remove FEIs. FMLS is also being integrated with Dunn and Bradstreet (DnB). DnB has one of the largest and most reliable databases on businesses in the world. This is being leveraged to improve the quality of firm information,			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		especially that related to foreign firms. This project focuses primarily on integrating with eLIST, improving survivorship rules and their application, and integrating with DnB. This provides MARCS FMS with access to higher quality data in regards to firms, which is used throughout the ORA regulatory work flows.			
287709	FDA ORA RBIS Report Development Support	The Online Reporting Analysis and Decision Support System (ORADSS) contains well over a thousand reports. This project will undertake a review of these reports to see what can be consolidated. In addition, it will provide a number of new reports to users. The types and number of reports is continually changing as the needs of users changes. ORADSS provides historical information and reporting capabilities to Mission Accomplishments and Regulatory Compliance Services (MARCS). Essentially, this makes every user of MARCS a user of ORADSS. As MARCS continues to build towards a unified data structure, this will require changes in ORADSS in order to provide historical information and reporting capabilities. These changes in MARCS will result in a number of changes to reports on the ORADSS side. In addition, ORADSS will also provide historical information and reporting capabilities for the Automated Laboratory Management (ALM) Laboratory			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		Management Information System (LIMS). LIMS is planning to produce pilots in FY12. This project will also lay the groundwork for providing reports for LIMS users.			
287710	FDA ORA RBIS Data Evaluation and Recommendations	RBIS has grown organically over time. With the recently awarded contract that places RBIS under one contractor, the changes in Mission Accomplishments and Regulatory Compliance Services (MARCS), and the expected addition of Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS), it is time to review the design of RBIS. This project will conduct a full review of the technical structure and implementation of the Online Reporting Analysis and Decision Support System (ORADSS) and Firm Master List Services (FMLS). RBIS provides the historical information, reporting capabilities, and firm information that are needed by MARCS and ALM. Changes in MARCS and ALM need to be accommodated in RBIS in order to provide end user functionality. This project will provide recommendations to the Government as to how to best restructure RBIS to handle expected future growth. This will also result in a road map to align RBIS future development with MARCS and ALM.			
287721	FDA ORA RBIS Data Availability	This project focuses primarily on the RBIS Online Reporting Analysis and Decision Support System (ORADSS) and provides			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		for changes to support Mission Accomplishments and Regulatory Compliance Services (MARCS) and Automated Laboratory Management (ALM). ORADSS provides historical information and reporting capabilities to MARCS and ALM. As MARCS continues to build towards a unified data structure, this will require changes in ORADSS in order to provide historical information and reporting capabilities. These changes in MARCS will result in a number of changes to reports on the ORADSS side. In addition, ORADSS will also provide historical information and reporting capabilities for the ALM Laboratory Management Information System (LIMS) and the ALM Quality Management Information System (QMiS). This will also provide for improvements in mapping capabilities regarding firm information. This will result in changes within ORADSS to the Data Warehouse (DW), many of the Data Marts (DMS), universes, and reports. ORADSS uses the COTS Business Objects as the basis for universe and reporting functionality.			
287722	FDA ORA RBIS Data Quality	This project focuses primarily on Firm Master List Services (FMLS). This includes additional Center integration, gray area resolution, additional support for Dunn and Bradstreet (DnB) integration, and improved integration with Mission			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		Accomplishments and Regulatory Compliance Services (MARCS) Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT) for validating firm information. FDA receives much firm information via Center systems, including FDA Unified Registration and Listing System (FURLS) and eLIST (no acronym). This will focusing on improving and automating more of this information transfer. Gray area resolution is used to resolve uncertainties regarding firm information when the survivorship rules used in FMLS do not produce a clear resolution. Survivorship rules are implemented via the COTS Dataflux and are an automated way to correct firm data, merge, unmerge, and delete Firm Establishment Identifiers (FEI). Manual gray area resolution is performed to tweak survivorship rules and manually resolve information discrepancies. DnB integration will be expanded, including a review of the current firm inventory in ORA and matching these against DnB information to produce a confidence level from 1 to 10 (10 is highest confidence) to support estimating the risk associated with a firm based on the quality of firm information. This will be used to support risk based decisions such as used for import screening. The method used to validate firm information from Customs and Border			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		Protection (CBP) that is then used by PREDICT in import screening will be modified to improve this, reduce latency, reduce uncertainty, and reduce reprocessing. FMLS in RBIS is closely aligned with Firm Management Services (FMS) in MARCS. FMLS does the back end heavy lifting work for managing firm information. As FMS is modified, FMLS will also be modified to support expanded functionality for MARCS users.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
287623	FDA ORA RBIS Center and External Integration							
287707	FDA ORA RBIS Data Warehouse, Data Marts, and Universes							
287708	FDA ORA RBIS Firm Master List Services (FMLS) Enhancements							
287709	FDA ORA RBIS Report Development Support							
287710	FDA ORA RBIS Data Evaluation and Recommendations							
287721	FDA ORA RBIS Data Availability							

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
287722	FDA ORA RBIS Data Quality							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
287623	287623: RBIS CEI Center Views	Validate requirements and functionality for Center Views	2011-10-30	2011-10-30	2011-10-30	90	0	0.00%

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Number of active users utilizing RBIS ORADSS per year. Making reporting capabilities available to end users enables them to complete their work. These reports are used throughout the ORA work flows. Supports Congressional Justification Performance Measure (CJ) 214205, 224201, 234202, 234203, 244202, 244203, 253201, 254201, and 214201.	# of active users utilizing RBIS ORADSS per year.	Customer Results - Service Accessibility	Over target	3000.000000	3500.000000	3612.000000	4000.000000	Semi-Annual
Number of firms cross matched with Dunn & Bradstreet (D&B) in RBIS FMLS. D&B contains information on firms worldwide. ORA uses this information to improve the quality of firm data that is used throughout the ORA work flows. This produces more accurate firm information for end users. Supports with CJ 214205, 224201, 234202, 234203, 244202, 244203, 253201, 254201,	# of firms cross matched with D&B per year.	Customer Results - Service Quality	Over target	0.000000	300000.000000	395085.000000	600000.000000	Semi-Annual

Table II.C.1 Performance Metrics								
Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
214201, 214202, and 214204.								
Number of objects available in RBIS ORADSS. This allows end users increased access to data without having to navigate the underlying data structures.	# of objects available in RBIS ORADSS.	Process and Activities - Productivity	Over target	5300.000000	5500.000000	5521.000000	5700.000000	Semi-Annual
Number of legacy reports remaining to be migrated. RBIS ORADSS is completing the migration of old reports to the FDA standard COTS reporting tool. This will standardize the development and maintenance of reports for ORA.	# of legacy reports remaining to be migrated.	Technology - Efficiency	Under target	100.000000	50.000000	32.000000	0.000000	Semi-Annual
Number of calls to the match and address validation service. RBIS FMLS is called to match firm information received with what is already in the firm database. Fuzzy logic is used to match received information to existing firm identifiers. If no current firm identifier can be matched, then a new firm identifier is made. This results in better information available for ORA	# of calls to match/address validation service.	Technology - Information and Data	Over target	300000.000000	350000.000000	412689.000000	400000.000000	Monthly

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
work flows. Supports with CJ 214205, 224201, 234202, 234203, 244202, 244203, 253201, 254201, 214201, 214202, and 214204.								